APPLICANTS: Bacus, et al
U.S.S.N.: 10/735,118

Remarks

Claims 84-110 were pending in this application. Claims 111-113 have been added; thus claims 84-113 are now pending.

Claims 84, 85, 87-89 and 101 have been amended. Claims 84 and 89 and have been amended to clarify that a particular polypeptide is assayed for either expression or phosphorylation. Support for these amendments can be found throughout the specification, for example in Tables 1-7. Claims 84 and 89 have also been amended to clarify that the pattern in the mammalian tumor is compared to a non-tumor tissue or cell type. Support for these claim amendments can be found throughout the specification, for example in paragraph 23 of the Summary of the Invention. Claim 101 has been amended to refer to the amendments made in claim 89. And finally, claims 87 and 88 have been amended to correct regretted typographical errors.

New claims 111-113 have been added to cover the method of claim 85 where the HER2-directed therapy comprises rhuMAb HER-2, where the sample obtained from the mammalian tumor is a paraffin-embedded biopsy sample, and where the mammalian tumor is identified as overexpressing HER-2 using an antibody that binds HER-2 polypeptide. Support for these new claims can be found, for example, in original claims 21, 37, and 39.

These new claim additions and claim amendments are being made prior to any substantive examination of the claims and, thus, are not being made for any reasons related to patentability. None of the above-amendments adds any new matter to the Application as filed.

Invention Election

The Restriction Requirement alleges that although the claims are drawn to either a process (Group I, claims 84-107) or a product (Group 2, claims 108-110), the claims of Groups 1 and 2 are patentably distinct because either (i) the process can be used with another materially different product or (ii) the product can be used in a materially different process. According to the Restriction Requirement, the product (namely the kit containing the antibodies) can be used to generate anti-idiotypic antibodies.

Applicant elects, with traverse, the invention of Group I (claims 84-107).

Applicants respectfully aver that examination of claims of both Groups I and II would not be unduly burdensome because of the close inter-relatedness of the claimed processes and the claimed kits. Further, Applicants respectfully aver that the materially different process alleged by the Restriction Requirement to which the antibodies of the Group 2 kit can be used, namely to generate idiotypic antibodies, is not a process that has a high likelihood of success. Rather, the ordinarily skilled artisan would understand that immunization of an animal with more than one antibody is likely to generate not an idiotypic response, but rather a non-specific immune response. Further, although there may be other processes in which the antibodies of the Group 2 kits can be used which have a higher likelihood of success (e.g., the antibodies of the claimed kits can be produced in large quantities for use as fish food), Applicants respectfully submits that the ordinarily skilled artisan, upon reading the specification, would realize that the most logical use for the claimed kits would be to perform the processes of the claims of the Group I invention. As the Supreme Court recently noted in KSR v. Teleflex 127 S. Ct. 1727 (2007), the ordinarily skilled artisan is not an automaton, but is rather a person with an ordinary amount of creativity. To deny Applicants the right to prosecute the invention of Group II in the instant invention is to invite the ordinarily skilled artisan to generate Applicants' claimed kit, with the only logical use for the kit being the practice of Applicants' invention of Group I. Applicants respectfully aver that the drafters of 35 U.S.C. 121 did not intent restriction requirements to be employed by competitors as a means to subvert the rights of patent holders. Therefore, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn, and that the claims of both Group I and Group II be examined together.

Species Election

The Restriction Requirement alleges that the claims of the invention of Group I are drawn to 1397 separate species.

Applicants elect, with traverse, the species of 1 for their elected invention of Group 1.

Applicants respectfully submit that they do not understand the reasoning behind this species election requirement, and therefore although Applicants are required to identify a claim that contains the elected species for either the invention of Group 1 or the invention of Group 2. However, Applicant believes that species 1 is present, at least, in claim 84 since claim 84 is the

first pending claim in the Application. To the extent that other claims (e.g., claim 85-113) also contain the species of species 1, Applicants with to include these claims as well.

Using claim 84, the first independent claim of the invention of Group I, as an example, Applicants were unable to identify 57 species. Rather, the claim, as currently amended, reads as follows:

> 84. A method for identifying a HER-2 over-expressing mammalian tumor that is likely to respond to a HER-2 directed therapy, the method comprising the steps of:
>
> (i) assaying a sample obtained from the mammalian tumor to detect a pattern of:
>
> (a) phosphorylation of an S6 ribosomal polypeptide;
>
> (b) expression of an IGFR (Insulin-like Growth Factor Receptor) polypeptide; and optionally
>
> (c) expression of a NDF (Heregulin) polypeptide; and
>
> (ii) comparing said pattern to a pattern detected in a sample obtained from a non-tumor tissue or cell sample,
>
> wherein a change in the detected pattern identifies said mammalian tumor as likely to respond to a HER-2 directed therapy.

Although none of Applicants and their representative is a trained mathematician or statistician, using their best efforts, Applicants were able to identify only the following combinations in claim 84, namely:

Phosphorylation of S6, expression of IGFR
Phosphorylation of S6, no expression of IGFR
Phosphorylation of S6, expression of IGFR, expression of NDF
Phosphorylation of S6, expression of IGFR, no expression of NDF
Phosphorylation of S6, no expression of IGFR, no expression of NDF
Phosphorylation of S6, no expression of IGFR, expression of NDF
No phosphorylation of S6, expression of IGFR
No phosphorylation of S6, no expression of IGFR
No phosphorylation of S6, expression of IGFR, expression of NDF
No phosphorylation of S6, expression of IGFR, no expression of NDF

No phosphorylation of S6, no expression of IGFR, expression of NDF
No phosphorylation of S6, no expression of IGFR, no expression of NDF

By Applicants' count, there are 12 species in claim 84. Applicants respectfully aver that the 14 species in claim 84 are not an unreasonable number of species to examine, particularly because all of the proteins are in the same class (Class 435) of search (see page 4 of Applicants' response mailed May 30, 2007).

Applicants respectfully note that they made the above calculation of the number of different combinations encompassed by claim 84 solely to make a bona-fide attempt to respond to the Restriction Requirement. Thus, the above calculation is not meant to limit Applicants' invention whatsoever, and should there in fact be more combinations in claim 84 than those listed above, Applicants is not making the representation that the invention encompassed by claim 84 should be limited to the above-listed twelve combinations. However, Applicants are required to elect a species and since from the Restriction Requirement, Applicants were unable to identify any single species, much less identify a claim that may be encompassed by that species, Applicants are providing the above calculation in a bona fide attempt to comply with the requirements set forth in the Restriction Requirement.

Finally, Applicants respectfully perverse the right to rejoinder of nonelected claims upon a finding of patentability of any linking claims.

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CONCLUSION

Applicants respectfully believe the elected claims are in good condition for allowance, and so further and favorable consideration on the merits of the claims of record is respectfully requested.

The six month due date for this Response, February 23, 2008, fell on a Saturday, and, accordingly, this Response should be considered timely filed on the following Monday, February 25, 2008 with the accompanying Petition for Five Month Extension of Time and payment of fees.

If there are any questions, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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